

14 AMENDT



Hormone Catheter, PCT/DK2003/000853

Coloplast A/S, 2002039 - WP

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**5 CLAIMS**

1. A device for urinary catheterisation comprising a catheter element adapted to be inserted in the urethra of a human, said catheter element comprising on the outer surface, before insertion of the catheter element, a pharmaceutically active composition comprising at least one agent selected from the group consisting of hormones, efferent blocking agents, afferent blocking agents and sympathomimetic agents, such that the pharmaceutically active composition is delivered to the lower urinary tract system during catheterisation.
2. A device according to claim 1, wherein said pharmaceutically active composition comprises a hormone.
3. A device according to claim 1 or 2, said device being provided in a sealed package, wherein a major part of said pharmaceutically active composition is present on an outer surface of the catheter element.
4. A device according to any of the preceding claims, wherein the pharmaceutically active composition is distributed over a section of the catheter element having a length of at least 50% of the total length of the catheter element.
5. A device according to any of the preceding claims, wherein the catheter element is adapted for intermittent catheterisation.
6. A device according to any of the preceding claims, wherein said catheter element is comprised in a female catheter.
7. A device according to any of the preceding claims, wherein said catheter element has a coating covering at least a portion of the outer surface of the catheter element and said coating contains at least a part of said pharmaceutically active composition and is adapted to release said pharmaceutically active composition within the lower urinary tract system.
8. A device according to any of the preceding claims, wherein at least a part of said catheter element has a polymer coating, and at least a portion of said polymer coating is impregnated with at least a part of said pharmaceutically active composition.

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9. A device according to any of the preceding claims, wherein at least a portion of said catheter element has a hydrophilic coating.
10. A device according to claim 9, wherein said hydrophilic coating is impregnated with at least a part of said pharmaceutically active composition.
- 5 11. A device according to any of the preceding claims, wherein said catheter element has depressions on the outer surface, which are adapted to hold at least a part of said pharmaceutically active composition.
12. A device according to any of the preceding claims, wherein at least a part of said pharmaceutically active composition is provided in a gel or crème.
- 10 13. A device according to any of the preceding claims, wherein said device is comprising a lubricating gel adapted to reduce friction between the catheter element and urethra, and said gel is containing at least a part of said pharmaceutically active composition.
14. A device according to any of the preceding claims, wherein said device is comprising a discrete unit dose containing said pharmaceutically active composition said device is adapted to shed said discrete unit dose in the lower urinary tract system.
- 15 15. A device according to any of the preceding claims, wherein said hormone is a female sex hormone or a derivative thereof.
16. A device according to claim 15, wherein said hormone is selected from oestrogen or an oestrogen derivative.
- 20 17. A device according to claim 15 or 16, wherein said hormone is oestriol or oestradiol.
18. A device according to any of the preceding claims, wherein said pharmaceutically active composition comprises an efferent blocking agent selected from the group consisting of anti-cholinergical agents, sympathomimetics agents, alfa-adrenergic agonists and nicotinic cholinergic agonists.
- 25 19. A device according to claim 19, wherein said efferent agent is oxybutynin or trospiumchlorid.
20. A device according to any of the preceding claims, wherein said pharmaceutically active composition comprises an afferent blocking agent.



21. Use of a pharmaceutically active composition comprising at least one agent selected from the group consisting of hormones, efferent blocking agents, afferent blocking agents and sympathomimetic agents, for the manufacture of a device for the treatment, alleviation or prophylaxis of incontinence in a human, said device comprising a catheter element  
5 adapted to be inserted in the urethra of said human, said catheter element comprising the pharmaceutically active composition, and said catheter element being adapted to deliver said agent in the lower urinary tract system during catheterisation.
22. The use according to claim 21, wherein the human is a female.
23. The use according to any of the claims 21-22, wherein the device is as defined in any of  
10 claims 1-20.
24. A method of treating a human suffering from or being susceptible to incontinence, the method comprising the steps of catheterisation of said human by arranging a proximal end of a catheter element of a device for urinary catheterisation in the urethra of said human, said catheter element comprising a pharmaceutically active composition comprising at least  
15 one agent selected from the group consisting of hormones, efferent blocking agents, afferent blocking agents and sympathomimetic agents, and said catheter element being adapted to deliver said composition in the lower urinary tract system during catheterisation.
25. The method according to claim 24, wherein the human is a female.
26. The method according to any of claim 23-24, wherein the device is as defined in any of  
20 claim 1-20.
27. A kit comprising a device for urinary catheterisation and a pharmaceutically active composition comprising at least one agent selected from the group consisting of hormones, efferent blocking agents, afferent blocking agents and sympathomimetic agents, said device comprising a catheter element adapted to be inserted in the urethra of a human.
28. A device for urinary catheterisation, said device comprising a catheter element with a proximal end adapted to be inserted in a urinary canal, characterised in that said device is comprising a discrete unit dose, said discrete unit dose comprising a pharmaceutically active composition and said catheter element being adapted to shed said pharmaceutically active composition in the lower urinary tract system during catheterisation.  
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29. A device according to claim 28, wherein said discrete unit dose is placed at the tip of the catheter.  
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